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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,483

03/22/2004

Hans-Juergen Kuhr

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EXAMINER

LANG, AMY T

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

10/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,483	Applicant(s) KUHR ET AL.	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 25-29, 33 and 35-37 is/are allowed.
- 6) ☒ Claim(s) 12-24, 30-32, 34 and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/10/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12-20, 34, 40, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i. In claims 12 and 34 there exists an inconsistency between the language in the preamble and the body of the claim, thus making the scope of the claims unclear. In the preamble, lines 1-2 of each claim, Applicant recites "a lancet system" with the lancing aid only being functionally recited, i.e. "for insertion into a lancing aid." This seems to indicate that the claims are directed to the subcombination, a lancet system. However, in line 15 of each claim Applicant positively recites the lancing aid as part of the invention, i.e. "actuated by interaction with a lancing aid." This seems to indicate

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the claims are directed to the combination, a lancet system and a lancing aid. As such it is unclear whether Applicant intends to claim the subcombination or the combination. Applicant is hereby required to indicate to which, subcombination or combination, the claims are intended to be directed and amend the claims such that the language thereof is consistent with this intent.

ii. Line 1 of claims 12 and 34 recite "a lancing aid." However, line 15 also recites "a lancing aid" so that it is unclear if the lancing aid in line 15 is that same as that in line 1 or if it is a different lancing aid. As such the claims are unclear and therefore indefinite.

Claims 13-20, 40, and 41 are dependent on claim 12 and therefore also rendered indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 21-24, 30-32, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVaughn et al. (US 2005/0015020 A1).

With regard to claims 21, 30-32, and 39, LeVaughn et al. (hereinafter LeVaughn) discloses a lancing aid (see entire document) comprising a lancing aid housing (4) and a needle housing (50) ([0094]; [0098]). The needle housing is configured for insertion into the lancing aid housing and removal after use ([0098; Figure 3). A plurality of needles (8), each having a tip, is arranged within the needle housing (Figure 4).

LeVaughn teaches in one embodiment wherein the lancet needles are able to move from a first resting position, in which the needle housing surrounds the tip, to a lancing position, in which the tip is exposed for puncturing a body part through drive mechanism (44) ([0109]; Figure 18). With this drive mechanism, a piston (154), spring (156), and trigger (162) are used to bring the lancet into a firing position ([0109]). The piston then returns to its starting position after it has completed its firing ([0109]). In this position, the needle is able to be moved again to the firing position by reactivating the piston, spring, and trigger. Although LeVaughn teaches that the resilient tongues (146) prevent re-firing of the needles ([0107]), LeVaughn teaches they only may be used in this embodiment and do not have to be used ([0109]). Therefore, when not utilizing the tongues in this embodiment, the needles are able to be re-fired.

In another embodiment, LeVaughn discloses wherein a control lever (202) is rotated so that a new lancet can be fired ([0113]). The lever (202) interacts with the needle housing (50) so that rotation of the lever activates the ring-shaped members

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(176) that remove the caps (174) from the needles and then activates the plunger (188) ([0110]; [0115]; Figures 17A-17D). Therefore, the interaction between the lever and the needle housing is essential to remove the lancet caps which then allow the plunger to be activated and fire the lancets. However, once all the needles in the needle housing have been used, all their caps have been removed. Therefore, once removing this used needle housing from the lancing aid would prevent re-use of the needle housing if reinserted into the lancing aid. Since all the caps have already been removed from the needles, the lever (202) would not be able to rotate to advance a new needle and activate the plunger ([0115]). As shown in Figures 17A-17D, the ring-shaped member (176), the blocking mechanism, has changed the shape of the needle housing by altering the position of the needles within the needle housing and by removal of the caps.

Although LeVaughn does not disclose the control lever from the second embodiment in the lancing aid of the first embodiment, such would have been obvious at the time of the invention. LeVaughn discloses two similar embodiments each with advantageous and beneficial lancing operations so that it would have been obvious to one of ordinary skill at the time of the invention to combine the two embodiments.

With regard to claim 22, the blocking mechanism, ring-shaped member (176), is actuated after the needle housing is inserted into the lancing aid ([0110]). Additionally, actuation of the blocking mechanism allows the needle to move into a firing position (Figures 17A-17D).

With regard to claim 23, LeVaughn further discloses a hole (26) through which the needle emerges when in a firing position ([0097]).

With regard to claim 24, the needle housing (50) comprises a magazine filled with a plurality of needles (8) (Figure 4).

With regard to claim 38, activation of the blocking mechanism (176) allows the needles to advance into a firing position and extend out of hole (26) (Figures 17A-17D). Therefore, as shown in Figure 17D, when the needle is extended out from hole (26), the outward circumference of the needle housing has enlarged. The blocking mechanism of LeVaughn allows this enlargement.

Allowable Subject Matter

7. Claims 1-11, 25-29, 33, and 35-37 are allowable. Claims 12-20, 34, 40, and 41 are allowable pending the above 35 USC 112 rejection.

Response to Arguments

8. Applicant's arguments, filed 07/10/2009, with respect to all previous rejections have been fully considered and are persuasive. The rejections have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/05/2009
/Amy T Lang/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
10/08/09